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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/696,174 | 10/29/2003 | Swaminathan Jayaraman | 795-A03-004 | 7393 |

33771 7590 07/18/2006

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| EXAMINER |
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PELLEGRINO, BRIAN E

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/696,174

Applicant(s)

JAYARAMAN, SWAMINATHAN

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/26/06 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 52,55,64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (5718159). Figs. 16,17 show a plurality of stent performs interlaced to form a stent. Thompson discloses the core strands are made of metal and can be shape memory alloy, col. 2, lines 61-65. Thompson also discloses the strands are coated with

therapeutic agents, col. 13, lines 35-45. It is inherent that the device to be used will include a doctor or surgeon determining vascular pathologies of a patient and what therapeutic agents would be effective for the patient. Thompson additionally discloses that the surgeon or doctor evaluates the implanted prosthesis in the patient, col. 13, lines 6,7.

Claims 52,54,56-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Parsons et al. (6521284). Fig. 2 shows a stent perform including an elongate core **2**, an outer sheath **6** disposed about the core and caps **4a,4b** on the ends of the sheath (col. 5, lines 29,30). Parsons et al. disclose the core is metal, col. 5, lines 12,13. Parsons also discloses a material in the pores of the outer sheath, col. 7, lines 13-18 and the sheath can be a polymer, col. 8, lines 59,60. Parsons additionally discloses the composition in the pores has incorporated within it therapeutic agents, such as two different agents, col. 12, lines 16-23. Parsons also discloses that a release mechanism or additional composition disposed on the sheath, col. 8, lines 15-17 and these compositions can be bioabsorbable, col. 9, lines 30-32.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. '284 in view of Mitchell et al. (5288711). Parsons et al. is explained supra. However, Parsons fails to disclose the therapeutic agents include rapamycin. Mitchell et al. teach that rapamycin is used on a stent (col. 7, lines 16-18) because it reduces intimal smooth muscle cell hyperplasia and reduces restenosis, col. 5, lines 3-8, 17-25. It would have been obvious to one of ordinary skill in the art to incorporate rapamycin with the vascular device as taught by Mitchell et al. with the vascular implant of Parsons et al. such that it aids in controlling the vascular response of hyperplasia that is primary cause of restenosis.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. '284 in view of Liprie et al. (6491662). Parsons et al. is explained supra. However, Parsons fails to disclose the mandrel or core is made of shape memory alloy. Liprie et al. teach that a mandrel or core is made of shape memory alloy to strengthen the vascular device, col. 2, lines 36-43. It would have been obvious to one of ordinary skill in the art to substitute metal materials and use a SMA as taught by Liprie with the device of Parsons such that it is flexible enough for delivery through a tortuous vessel, but stiff enough to not crimp.

Claims 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. '284 in view of Sukhatme (2005/261283). Parsons et al. is explained supra. However, Parsons fails to disclose the method of treating a vascular disease and the use of rapamycin with the drug imatinib mesylate in combination. Sukhatme teaches a method of treating a vascular disease by determining a pathologic process

resulting from a disease and selecting therapeutic agents to treat the disease, paragraph 16. Sukhatme also teaches that rapamycin and imatinib mesylate can be used to effectively treat hyperplasia, paragraphs 117,151,164. Sukhatme also teaches that the devices are implanted and the patient is monitored, paragraph 260.

Response to Arguments

Applicant's arguments with respect to new claims 52-69 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

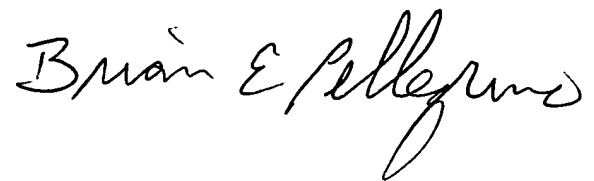
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Brian E. Pellegrino". The signature is written in black ink and is positioned below the printed name and title.